

Arguments/Remarks

Claims 1-8 are pending and presently under rejection. Claims 1 and 5 have been amended. Withdrawal and reconsideration of the rejections are respectfully requested.

Rejections under 35 USC 112

The Examiner has rejected claims 1-8 under 35 USC 112 first paragraph as containing claimed subject matter which was not adequately enabled by the specification. More particularly, the claims Examiner alleges that the claims for the prevention of NHL, or the prevention or treatment of all conditions susceptible to treatment with an ALK inhibiting agent are not enabled.

It is well established however, that if *in vitro* tests correlate to a claimed method of invention, it constitutes a working example sufficient to provide enablement of the claims. See, e.g., MPEP 2164.02. This is particularly the case in instances where the state of the art recognizes such a correlation. In the present case, the compounds of the invention were shown to potentially inhibit activity of ALK tyrosine kinase, as demonstrated on pages 30-31 of the specification.

Furthermore, in order to more accurately describe the inventive subject matter, applicants have amended the application for the specific indications of anaplastic large-cell lymphoma, ALKomas and inflammatory myofibroblastic tumors. The rejection is respectfully traversed. Reconsideration and withdrawal are respectfully requested.

Rejection under 35 USC 102

The Examiner has rejected the claims under 35 USC 102(e) as being anticipated by commonly owned Baenteli et al (WO 03/078404). The rejection is respectfully traversed.

For a rejection to be proper under 35 USC 102, each and every claimed element must be present in the anticipating reference. The rejection is improper in this case because Baenteli does not disclose "a method of treating a condition susceptible to treatment with an ALK inhibiting agent which comprised inhibiting ALK or a gene fusion thereof with a compound of formula I." Further, applicants have amended the claims to specific indications not disclosed in Baenteli.

The Examiner acknowledges that Baenteli does not disclose or teach the ALK inhibitory effect of the compounds, but indicates that, "this activity is a property of the compound and is necessarily present" (Office Action, page 6, first full paragraph, lines 6-8). The Examiner, in other words, is claiming the property to be inherent in the prior art.

In order to establish inherency however, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill in the art. See MPEP 2112.IV. In the present case, the compounds of Baenteli were disclosed as being useful in treating diseases or conditions in which ZAP-70, FAK, or Syk tyrosine inhibition activity is implicated. The compounds are identical to those of the presently claimed method of treating diseases associated with ALK inhibition. The amended claims also specifically relate to indications associated with ALK inhibition.

One of skill in the art would not recognize the compounds of Baenteli as being useful in treating or preventing a condition susceptible to treatment with an ALK inhibiting agent. The Examiner has further offered no suggestion that one of skill in the art would recognize the utility of Baenteli's compounds in the presently claimed method. Withdrawal and reconsideration are respectfully requested.

Should the Examiner have any questions, please contact the undersigned attorney.

Respectfully submitted,



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